IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

EARL RINGO JR. et al. Plaintiffs,	)	
v.	)	09-4095-CV-C NKL
GEORGE A. LOMBARDI et al., Defendants.	)	

MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Motion for Summary Judgment

Introduction

Earl Ringo Jr. and his co-plaintiffs are Missouri inmates under sentence of death for murder. Plaintiffs allege that they will be executed by using controlled substances that will not be administered or prescribed by a medical practitioner, and that this violates the Controlled Substances Act and the Food Drug and Cosmetic Act. Plaintiffs also allege that it violates the Food Drug and Cosmetic Act that a board certified anesthesiologist as opposed to a pharmacist adds saline to the sodium thiopental powder used in lethal injections. Finally, Plaintiffs allege that it violates the Food Drug and Cosmetic Act to execute Plaintiffs by lethal injection because the chemicals used in executions by lethal injection are not approved by the Food and Drug Administration for use in executions by lethal injection and the physician does not write a prescription for off label use

(Amended Complaint Document 168 at 23-26). Plaintiffs ask for both declaratory and injunctive relief. (Amended Complaint 26-27).

The complaint must fail for several reasons. These include the following reasons. The evidence does not support a claim that Plaintiffs have standing in that Plaintiffs fail to establish an injury in fact, caused by Defendants that would be remedied by a favorable decision. The Plaintiffs are attempting to privately enforce statutes that may only be enforced by the Executive Branch of the Federal Government. The Defendants in this case are immune from suit. The suit is without legal merit. Defendants move for summary judgment on all claims.

Statement of Exhibits

Defendants rely on the following exhibits in moving for summary judgment.

Exhibit 1 (sealed) is the deposition of M-2 the nurse on the execution team.

Exhibit 2 (sealed) is the deposition of M-3 the board certified anesthesiologist on the execution team.

Exhibit 3 is the Training Plan for Execution Team Members (Ringo pp 359-395) marked as a deposition exhibit by Plaintiffs.

Exhibit 4 is "Preparation and Injection of Lethal Chemicals" (Ringo 1-4) marked as a deposition exhibit by Plaintiffs.

Exhibit 5 is the deposition of the business manager of the institution where executions are carried out.

Exhibit 6 is the deposition of the man who was the Director of the Division of Adult Institutions at the time of his December 22, 2010 deposition. The Director's last day working was January 20, 2011.

Exhibit 7 is the Deposition of the Director of the Missouri Department of Corrections.

Exhibit 8 is a copy of current and former registrations of the Bonne Terre Correctional Center for possessing controlled substances and a supporting affidavit.

Legal Memorandum in Support of Motion for Summary Judgment

Table of Contents

Table of Authorities

Cases

Statutes

Statement of Uncontroverted Material Facts

1 The Food and Drug Administration has expressed the position that it does not regulate or approve chemicals for use in executions by lethal injection. *Heckler v. Chaney*, 470 U.S. 821, 824-825 (1985). (FDA Director indicates FDA does not have jurisdiction over the use of chemicals in executions by lethal injection and would not exercise such jurisdiction if it existed).

2 The FDA still takes the position that "Reviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside the FDA's explicit public health role." (January 4, 2011 FDA statement quoted in "FDA Takes Stance on the Importation of Lethal Injection Drugs" http://blogswsj.com/law/2011/01/04,- Wall Street Journal online).

3 The Eastern Reception Diagnostic Correctional Center, where executions are carried out, has registrations with the DEA and the Missouri State Government allowing it to possess controlled substances (Exh. 8 Registrations and Supporting Affidavit; Exh. 7 Deposition of George Lombardi at 21-24, 28).

4 The business manager for the Eastern Reception Diagnostic Correctional Center purchases the chemicals used in executions by

lethal injection from a pharmaceutical supplier. (Exh. 5 at 10-11; Deposition of Business Manager).

5 The three chemicals used in execution by lethal injection are sodium thiopental, pancuronium bromide, and potassium chloride (Exh. 4 "Preparation and Injection of Chemicals").

6 Medical personnel offer the offender a sedative which is an oral valium tablet approximately around 7:30 p.m. on the night of the execution (Exh. 2 Deposition of Doctor at 363, 384). A second sedative is offered around 11:20 p.m. (Exh. 2 at 384).

7 The nurse only gives the offender a valium tablet if requested by the offender. The nurse would not under any circumstances give Versed, Ketamine or Haldol as sedatives as these would only be administered by the physician (Exh. 1 Deposition of Nurse at 111-112).

8 The physician who is a member of the execution team is a board certified anesthesiologist (Exh. 2 at 7).

9 The board certified anesthesiologist has active registrations with the Drug Enforcement Agency and the Bureau of Narcotics and Dangerous Drugs to possess and use controlled substances (Exh. 2 at 7-8).

10 When a physician administers an anesthesia drug in a health care setting he is not required to, and does not, write a prescription for the drug if he administers it himself or it is administered by a physician or a person

under his direct control (Exh. 2 at 68-71). There is never an occasion to write a prescription for an anesthesia drug (Resp. Exh. 2 at 72).

11 The board certified anesthesiologist mixes normal saline, into prepackaged vials of sodium thiopental powder (Exh. 2 at 47-48).

12 Anesthesiologists normally do this mixing as residents, but when they become an attending physician "you have people do it for you" (Exh. 2 at 48-49).

13 The maximum dose of sodium thiopental that would be used in surgery is one half gram, and ten times as much, five grams is used in an execution. This is amount is sufficient to cause death by itself (Exh. 2 at 57).

14 Pancuronium bromide is a muscle relaxant that stops breathing, and potassium chloride stops the heart muscle (Exh. 2 at 57).

15 The anesthesiologist occasionally uses pancuronium bromide in his practice. He would use 15 to 20 milligrams for a three hour surgery. Sixty milligrams is used in a lethal injection. This amount would cause complete paralysis for six to eight hours (Exh. 2 at 73-77).

16 The line is flushed between the use of the sodium thiopental and the pancuronium bromide so that there is no possibility of the chemicals mixing and forming a precipitate (Exh. 2 at 80).

17 Two hundred forty millequivalents of a potassium chloride are given to stop the heart (Exh. 2 at 60).

18 The pancuronium bromide and potassium chloride are pre-mixed and ready to be used (Exh. 2 at 87).

19 The board certified anesthesiologist adds a set amount of saline solution to each vial of sodium thiopental powder then draws up the syringes to be administered to offender (Exh. 2 at 88-92).

20 The nurse draws up the syringes of the pre-mixed chemicals pancuronium bromide, and potassium chloride (Exh. 2 at 94-95).

21 The anesthesiologist inserted the IV at the last execution because "I'm an expert" although the nurse was qualified to do so (Exh. 3 at 101-102).

22 The nurse is IV certified and highly experienced in setting IV's, having set five to twenty a month for around twenty years (Exh. 1 at 44-46).

23 It is the anesthesiologist's practice to use numbing medication (lidocaine) when he inserts the IV to relieve discomfort (Exh. 2 at 104).

24 The lethal chemicals are injected in a port in the IV (Exh. 2 at 120-121).

25 The anesthesiologist hands non-medical personnel the syringes to inject into the port, watches them inject the chemicals into the port, as he has practiced with them, and puts the caps back on each needle as each syringe is completed (Exh. 2 at 121).

Standing

The irreducible constitutional minimum for a plaintiff to have standing to pursue a case in a federal court is that the plaintiff has suffered an injury in fact fairly, traceable to the challenged action of the defendant, and it must be likely that the injury will be redressed by a favorable decision *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-56 (1992). To be an injury in fact an injury must be an invasion of a legally protected interest which is concrete and particularized, and actual or imminent as opposed to conjectural or hypothetical. *Id*. 560.

The party invoking federal jurisdiction bears the burden of establishing these elements *Id*. at 561. In responding to a motion for summary judgment the plaintiff must set forth by affidavit or other evidence specific facts that establish the elements of standing. *Id*. at 561.

Plaintiffs' count 1 complains the Controlled Substances Act (CSA) will be violated during an execution because sodium thiopental will be administered without a prescription by a person who is not a licensed medical professional (Amended Complaint at 23-24). Plaintiffs also complain that Ketamine (a sedative) midazolam (a sedative also known as versed), and diazepam (a sedative also known as valium) will be administered without a prescription by a person not licensed and registered to administer these substances (Amended Complaint at 24). Plaintiffs specifically allege a violation of 21 U.S.C. 829(b) which requires that schedule III and IV controlled substances be dispensed by an oral or written prescription unless dispensed by a licensed practitioner other than a pharmacist,

and 21 U.S.C. 822(a) which requires that a person who manufactures or distributes controlled substances to have a registration.

The chemicals used in lethal injections are obtained from a pharmaceutical company by the business manager of the Eastern Reception, Diagnostic Correctional Center, an institution registered by the State and the Federal Government to possess controlled substances, (Exh. 7 at 21-24, 28; Exh 8; Exh. 5 at 10-11). A board certified anesthesiologist, who is registered to possess and use controlled substances, adds saline solution to the sodium thiopental, draws it up in syringes and hands the syringes to the person who injects the syringes into a port in the IV line, as the anesthesiologist observes (Exh. 2 at 7-8, 47-48,121). If any sedatives other than valium are to be given to the offender (including ketamine and versed) these would only be administered by the physician (Exh. 1 at 111-112).

Plaintiffs' factual complaint in count 1 therefore reduces to the complaint that the anesthesiologist hands the syringe containing sodium thiopental to the person who injects the chemical into a port in the IV while the anesthesiologist observes but does not write a prescription before handing the syringe to another person, and that the nurse offers the offender a valium tablet for which the physician does not write a prescription. Plaintiffs also may be making some type of complaint about the purchase and possession of the chemicals by the institution. Assuming for the sake of argument that this conduct can be plausibly characterized as a violation of 21 U.S.C. § 822(a) or 21 U.S.C. §829, which is at

best a questionable proposition, and assuming that the Controlled Substances Act has any application at all in the context of executions, also a questionable proposition -*See Gonzales v. Oregon*, 546 U.S. 243, 272 (2006) (noting, in rejecting an attempt to use the CSA to prevent the use of controlled substances in legal assisted suicides, that the CSA is "a statute combating recreational drug use")-, Plaintiffs still must show that they suffer an injury in fact in order to challenge the alleged violations of the statute.

Plaintiffs cannot show an actual or imminent, concrete, and particularized invasion of a legally protected interest of Plaintiffs in the fact pattern of this case. Plaintiffs do not suffer an injury in fact because the anesthesiologist does not write a prescription for the nurse to offer to dispense a valium tablet, or for the person who pushes the plunger on the syringe in the IV port to push the plunger, nor because the chemicals are bought by the institutional business manager as opposed to by the physician personally. If the physician wrote a prescription no injury would be averted that occurs because he does not do so. In fact these actions are not close to rising to the level of an injury in fact. *See Spencer v. Kemna*, 523 U.S. 1, 14-18 (1998) (finding no standing to challenge an allegedly unconstitutional parole revocation for, among things, rape, after the expiration of the sentence and conviction for a new crime, because the alleged injuries of detriment in future parole hearings, possible increase in future sentences, possible use as impeachment, or as direct evidence in criminal proceedings, do not rise to the level of injury in fact).

Count 2 is a similar claim, but based on the Food Drug and Cosmetic Act (FDCA). Plaintiffs challenge the administration of the actual execution drugs sodium thiopental, pancuronium bromide, and potassium chloride without a prescription as well as the potential use of ketamine, midazolam, heparin (an anti-coagulant), romazicon (an antidote to certain sedatives such as valium), lidocaine (a numbing agent) and methyline blue (a blue dye) (Amended Petition at 24-25). Plaintiffs allege these chemicals will be administered by "non-medical personnel" (Amended Petition at 24-25). Further Plaintiffs allege that one or more drugs including sodium thiopental are mixed, compounded or prepared by someone other than a pharmacist and that this violates the FDCA.

The amended complaint does not allege the violation of a specific provision of the FDCA. The actions prohibited by the FDCA are listed at 21 USC §331. Title 21 USC §331(k) bars altering or misbranding a food, drug or cosmetic while holding it for sale. Another provision, 21 USC 353(b)(1), describes dispensing a drug that is only safe for use under the supervision of a licensed medical practitioner as a form of misbranding a drug while holding it for sale. That was the provision alleged to be violated by lethal injection in the *Chaney v. Heckler* litigation. *See Chaney v. Heckler*, 718 F.2d 1174, 1199 (D.C. Cir. 1983) (Scalia J. dissenting)(stating, referring to drugs used in executions by lethal injection, "under no conceivable interpretation of the English language could they be deemed held for sale"). Assuming for the sake of argument that the FDCA has any application to executions by lethal injection which it probably does not –*See Heckler v.*

Chaney, 470 U.S. 821, 824-825 (1985) (FDA Director opines the Agency probably does not have jurisdiction over executions)-, and assuming that some provision of the FDCA can somehow be read to be violated by Missouri executions, Plaintiffs still must show an injury in fact to have standing to challenge the alleged violation.

Plaintiffs cannot show an injury in fact. The only chemicals administered by non-medical personnel are the sodium thiopental, pancuronium bromide, and potassium chloride –a syringe of saltwater used to flush the line is also injected by non-medical personnel (Exh. 4 "Preparation and Injection of Chemicals"; Exh. 5 Training Manual). The extent of the administration by non-medical personnel is that these chemicals are injected from already prepared syringes into an injection port on the IV tube under the observation of the anesthesiologist (Exh. 2 at 120-121). The sodium thiopental is the only chemical mixed and the mixture consists of the anesthesiologist adding saline solution (salt water) to vials of sodium thiopental powder (Exh. 2 at 88-92). The extent of any potential injury in fact to Plaintiffs therefore must necessarily arise either from the anesthesiologist mixing the sodium thiopental with saline solution, as opposed to having a pharmacist do it for him, or from the non-medical personnel injecting sodium thiopental, pancuronium bromide, and potassium chloride into the IV portal without a prescription while being observed by the anesthesiologist, rather than the anesthesiologist pushing the plunger himself or writing a prescription someone else to do it. Neither of these actions comes close to being an injury in fact to

Plaintiffs. A prescription does not make the process safer, and no injury to Plaintiffs would be cured by writing one. The actual pushing of the plunger is done under the observation of the anesthesiologist by persons trained to do that task. And a board certified anesthesiologist is capable of adding salt water to a powder in a vial.

In Count III Plaintiffs allege that an unspecified provision of the FDAC is violated because the chemicals used in lethal injections although approved for use by the FDA are not approved for use in lethal injections and the physician does not write a prescription for their use in this manner (Amended Complaint at 25-26). The FDA does not approve chemicals for use in executions by lethal injection viewing that activity as outside its function. *See Heckler v. Chaney,* 470 U.S. 821, 824-825 (1985); "FDA takes Stance on the Importation of Lethal Injection Drugs" http://swsj.com/law/2011/01/04). Assuming for the sake of argument that the FDA is wrong in believing the FDCA does not regulate lethal injections, and that the use of chemicals in the lethal injection process without FDA approval or a prescription for their use in lethal injections somehow violates the FDCA, Plaintiffs still must show an injury in fact traceable to Defendants and likely to be resolved by a favorable decision.

There is no injury in fact to Plaintiffs because the chemicals used in the lethal injection procedure are not approved by the FDA for use in lethal injections or prescribed by the physician. Plaintiffs have not alleged any evidence exists and cannot establish that they are actually harmed in any way because the chemicals

used in lethal injections are not approved by the FDA for that purpose. If the physician were to write a prescription, for an off label use that would have no practical effect on Plaintiffs, and the lack of a prescription causes no injury. Further, because the FDA is not in the business of approving chemicals for use in lethal injections and there is no reason to believe it will ever be in that business, any alleged harm from the failure to use chemicals approved for use in lethal injections is not traceable to Defendants, and cannot really be remedied by a favorable judicial decision in this case.

The Plaintiffs are Improperly Attempting to Enforce Statutes that may Only be Enforced by the Executive Branch of the Federal Government

In granting partial judgment on the pleadings for Defendants this Court, agreeing with *Durr v Strickland,* Slip op. 2:10-cv288, 2010 WL 1610592 (S.D. Ohio, April 15, 2010 *aff'd* 602 F.3d 788 (6th Cir. 2010) found that this action is an improper attempt to privately enforce the FDCA and the CSA, and found "As to Plaintiffs' claim seeking a declaratory judgment that the State is violating the CSA and the FDCA, the Court grants judgment on the pleadings for the Defendants" (Document 138 at 3). But this Court allowed the case to continue on the issue of whether Plaintiffs make out a claim for preemption of Missouri's execution statute or protocol by federal law, finding that the question "is not properly decided on a motion for judgment on the pleadings" (Document 138 at 5).

Recent challenges to state execution by lethal injection procedures, as violating the FDCA and the CSA, have been rejected by the United States District

Court for the Southern District of Ohio and the United States Court of Appeals for the Sixth Circuit in *Durr v.Strickland*, by the Supreme Court of Washington in *Brown v .Vail*, 263 P.3d 263(2010); by the United States District Court for the Western District of Washington in *Brown v. Vail*, Slip op. C-09-5101 (W.D. Wash Aug. 31 2010), by the United States District Court for the Eastern District of Kentucky in *Bowling v. Haas*, Slip Op. 3: 07-032KKC 2010 WL 32825467 (E.D. Kentucky Sept 23, 2010), by the United States District Court for the Eastern District of Arkansas in *Jones v. Hobbs*, Slip. Op. 5:10-cv-0065 JLH 2010 WL 2985502 (E.D. Ark. July 26, 2010), by the United States District Court for the Middle District of Tennessee in *West. v. Ray*, Slip op. 3:10-0778 (M.D. Tenn. Sept. 24, 2010), and by the Supreme Court of Tennessee in *Tennessee v. Harbison*, Slip op. M1986-00093-SC-OT-DD (Tenn. Oct 12, 2010)(per curiam)(denying petition for rehearing on an order to set execution date, alleging Tennessee execution procedures violate the FDCA and CSA).

The key principle that links theses case together is that Congress intended the Acts to be enforced only by the Federal Executive, and Congress made no exception from that intention for what are in reality private enforcement actions against the States by private individuals. There is no truly plausible way to distinguish cases such as *Durr, Jones, Brown, Bowling,* and *West* from this case. If the courts in those cases accepted the analysis that those cases could have continued under a preemption theory, the cases would have continued. But they did not continue. In *Bowling* the district court, described this case (*Ringo*) as " an

action involving identical claims" (*Bowling* at 3), noted that Bowling relied on the Supremacy Clause (*Bowling* at 5), and found that the question of whether a state actor had complied with these statutes must be asked by federal law enforcement officials in the first place (Bowling at 6). The district court in *West* acknowledged that this Court allowed this case to continue on the theory that the claim hinged on the supremacy of federal law rather than individual rights but found that the courts in the *Jones* and *Durr* cases did not make that distinction and concluded that letting the case continue would "evade the intent of Congress" and "circumvent the discretion entrusted to the executive branch" (*West* at 3-4). The clear intent of Congress that the FDCA be enforced by the FDA and not private citizens and that the CSA, a statute with criminal penalties, be enforced by the Attorney General cuts off any cause of action by individuals under a preemption theory against state officials just as it does other private actions to enforce the statutes.

The Plain Statement Rule

Additionally, the intention of Congress to regulate executions would be an exercise of control over an area traditionally left to the States and would alter the usual balance between the States and the Federal Government. In such a case the intention of Congress to exercise control over the area traditionally left to the States must be unmistakably clear or it is presumed not to exist. *See Oregon v. Ashcroft*, 368 F3d 1118, 1124-1125 (9th Cir. 2004) (applying the plain statement rule standard of unmistakable clarity to reject a claim that Congress intended that the CSA could be used to regulate physician assisted suicides using controlled

substances even though physician assisted suicides are permitted by Oregon law) *aff'd Gonzalez v. Oregon,* 546 U.S. 243,274 (2006) (Supreme Court finds that applying prescription requirements of CSA to ban physician assisted suicides would intervene in an area traditionally reserved to the States but that it was unnecessary to reach the level of analyzing "clear statement requirements" to reject the claim that the statute authorizes a ban on physician assisted suicide) ; *See also Gregory v. Ashcroft*, 501 U.S. 452, 460-461(1991)(applying the unmistakable clarity standard to reject the idea that the Age Discrimination in Employment Act applies to state judges in the face of a state statute mandating judicial retirement at age 70); *Nixon v. Municipal League*, 541 U.S. 125 (2004) (using the plain statement requirement of unmistakable clarity in rejecting a claim that the term "any entity" in the Telecommunications Act of 1996 included municipalities that sought to provide telecommunications services contrary to Missouri law). The plain statement rule controls in the area of legal executions of criminals, because that area has traditionally been left to the States by Congress, and there is no plain statement in the CSA or the FDCA that those Acts are meant to regulate executions by lethal injection. The analysis by the Ninth Circuit Court of Appeals in *Oregon v. Ashcroft* rejecting a claim that the CSA could be used to regulate or prohibit physician assisted suicide is particularly instructive. *See Oregon*, 368 F.3d at 1125(finding that unless the authorization by Congress is "unmistakably clear" the Attorney General cannot exercise control under the CSA over an area traditionally reserved for state authority and that Congress has

provided no unmistakably clear indication it intended the Attorney General to be able to use the CSA to regulate physician assisted suicides). *See Id*. at 1126 (stating that physician assisted suicide is an unrelated general medical practice to be regulated by state law makers in the first instance and that "We know Congress intended to limit federal authority under the CSA to the field of drug abuse"). It is illogical that Plaintiffs have a cause of action that survives only because it is brought against state actors, when the plain statement rule would bar the officials charged with enforcing the statute raising the same claim against the same Defendants. The same bar applies to Plaintiffs. The lack of a plain statement by Congress that it intended the FDCA & CSA to be enforced in the context of executions for state criminal convictions, an area traditionally left to the States by Congress, reinforces the conclusion that Plaintiffs have no cause of action to pursue.

But even without the plain statement rule, the clear intent of Congress that the Acts be enforced only by the Federal Executive would cut off a preemption suit that seeks to enforce the Acts against State officials as well as suits against private individuals, as that intent is clear from the Acts themselves. Defendants will now analyze the case in the context of Eleventh Amendment immunity. But even absent Eleventh Amendment immunity, the analysis would reach the same result as the cases cited above rejecting or identical or similar claims.

Eleventh Amendment Immunity

Defendants have asserted and continue to assert Eleventh Amendment immunity from suit in this case (Document 148).The *Ex Parte Young* exception to Eleventh Amendment immunity, for claims alleging a conflict between state and federal law seeking only prospective relief, is itself subject to exceptions. Those exceptions include cases in which a "federal statutory scheme evidences an implicit or explicit intent to exclude *Ex Parte Young* actions" and cases in which "the suit and remedy implicate special sovereignty interests such that an *Ex Parte Young* action will not lie." *Union Electric Company v. Missouri Department of Conservation*, 366 F.3d 655, 658 (8th Cir. 2004).[1]

The analysis under the first exception is not whether Congress intended to exclude all *Ex Parte Young* actions under the statutory scheme but rather whether Congress intended to exclude the particular type of *Ex Parte Young* action in the case before the court. *Id*. at 658. In *Union Electric* the Missouri Department of Conservation sued a utility company in state court for 3.256 million dollars in damages that resulted from a fish kill. The utility company brought a suit for declaratory and injunctive relief in federal court alleging that any state court or administrative actions to impose liability were preempted by the Federal Power Act. The United States Court of Appeals found that the Act by stating that licensees were liable for damages to the property of others without making a

[1] The first exception arose in *Seminole Tribe of Florida v. Florida*, 544 U.S. 44, 74-75 (1996), a case in which the Court took the provision of a comprehensive enforcement scheme targeted at the states as evidence of intent that Congress had not meant to authorize *Ex Parte Young* suits for the same enforcement purpose.

distinction based on whether the damaged parties were private individuals or states demonstrated intent that *Ex Parte Young* actions could not be brought seeking to prevent states from recovering damages. *Id.* at 658.

The Food Drug and Cosmetic Act provides a detailed remedial scheme and specifically states that proceedings to enforce or restrain violations of the Act "shall be by and in the name of the United States." 21 U.S.C. §337. The Act makes no exception for a case where a state or state official is a proposed defendant. The type of suit Plaintiffs are bringing in this case, like the suit in *Union Electric* is contrary to the intent of the Act and is futile. It is difficult to see how Congress could have made its intent to bar private attempts to restrain alleged violations of the FDCA any clearer. Such suits by private individuals are explicitly banned regardless of who the defendant is and whether or not the relief sought is prospective, and allowing such suits to proceed is contrary to the intent of Congress. Therefore the suit cannot breach Eleventh Amendment immunity under *Union Electric* and *Seminole Tribe*, whether or not it is called a preemption action and the defendant is a state official, because it is the intent of Congress that such actions not occur at all.

Similarly, the CSA also provides a detailed remedial scheme for alleged violations of that Act, to be enforced by the Attorney General of the United States with sanctions including actions against registrations, fines, and criminal penalties. *See* 21 U.S.C.§§ 821, 824, 844-846. The statute makes no distinction permitting private enforcement against state actors. In fact it explicitly grants immunity from

civil and criminal penalties to state and local law enforcement officers enforcing any law related to controlled substances. 21 USC §885(d). It is not necessary to analyze whether the grant of immunity in §885(d) applies to execution by lethal injection. But at least one court has held that it does. *See Brown v. Vail*, Slip. op. at 19, C09-5101-JCC (W.D. Wash. Aug. 31, 2010) (holding that private rights of action are unavailable under the FDCA and CSA, and that even if they were not unavailable, 21 U.S.C.§885(d) provided an alternate reason for dismissing the suit). The key question for analysis under *Union Electric* is the intent of Congress not to permit the type of *Ex Parte Young* suit that is being prosecuted. The structure and provisions of the statute evidence Congressional intent not to permit the type of *Ex Parte Young* actions that Plaintiffs bring in this case. It is Congressional intent that is critical. The structure and provisions of the statute are only the evidence of that intent. As with the FDCA, the presence of a detailed remedial scheme to be enforced exclusively by the Federal government in the CSA and FDCA is simply inconsistent with the existence of *Ex Parte Young* suits that are in reality private enforcement actions against the States. Such suits cannot breach the immunity of the several states to suit under the Eleventh Amendment to the United States Constitution.[2]

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[2] The clear intent of Congress not to permit what are in essence private enforcement actions of the CSA and FDCA should in Defendants' view prevent such actions regardless of whether the defendant is a state official attacked under a nominal preemption theory and regardless of whether Eleventh Amendment immunity is asserted. Similar suits were cut off in *Durr v. Strickland*, *Jones v. Hobbs*, and *Brown v. Vail* , *Bowling v. Haas*, and. *West v. Ray* without the

Additionally, the plain statement rule of *Oregon v. Ashcroft*, *Gregory v. Ashcroft*, and *Nixon v. Municipal League* should also have a role in Eleventh Amendment analysis. Although Defendants prevail under *Union Electric* and *Seminole Tribe* based on the clear intention of Congress that the Acts not be privately enforced against anyone, without using the plain statement rule, the plain statement rule also cuts strongly against there being Congressional intent to enforce the CSA and FDCA through *Ex Parte Young* actions in the case of executions, an area traditionally within the regulation of the Several States and in which regulation would represent a shift in the traditional balance of federal and state responsibility. Therefore the plain statement rule is a sufficient but not necessary means of establishing immunity from an *Ex parte Young* suit under the exception described in *Union Electric* and *Seminole Tribe*, as well its more general use in analyzing whether a cause of action exists in general.

Merits Analysis

Plaintiff's Count 1 is an assertion that that the CSA will be violated because controlled substances will in the process of an execution by the State allegedly be obtained and administered without a prescription by someone other than a licensed medical professional in violation of 21 U.S.C. 822(a) and 21 U.S.C. 829(b). (Amended Complaint at 23-24). In *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006)

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necessity of reliance on Eleventh Amendment immunity. But Defendants assert Eleventh Amendment immunity, and under *Union Electric* and *Seminole Tribe* that assertion also should end the case.

the United States Supreme Court defined the main objectives of the CSA as combating drug abuse, and controlling the legitimate and illegitimate traffic in controlled substances. The Court found that read in context the prescription requirement "is a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse….As a corollary, the provision also bars doctors from peddling to patients who crave drugs for those prohibited uses." *Id*. at 274. The Court concluded that the use of prescription drugs in physician assisted suicides is not "drug abuse" banned by the statute. *Id.* The Court held that "we conclude the CSA's prescription requirement does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct." *Id*. at 274-275. The Court also noted that this was an area traditionally regulated by the States but that it is "unnecessary to even consider the application of the clear statement requirements" *Id*. at 274. *Gonzalez* v. *Oregon* is on point. Plaintiffs are essentially reading provisions of the CSA out of context in order to find violations from conduct that is not banned by the statute, and it is not necessary to reach the level of analyzing plain statement requirements, as the Ninth Circuit Court of Appeals did in *Oregon v. Ashcroft*, to be firmly convinced of that conclusion. But to reach the opposite conclusion, that the claim has merit, the claim would have to withstand plain statement analysis. It cannot. The count fails on the merits as a matter of law based on both simply reading the statute in context, and based on the use of plain statement rule as a tool of statutory

interpretation in this area traditionally regulated by the States as opposed to by Congress. As the United States Supreme Court pointed out in *Gonzalez v. Oregon*, the prescription requirements of the CSA are meant to prevent addiction, recreational abuse, and peddling drugs to addicts and recreational users. Just as those provisions do not authorize using the Act to regulate physician assisted suicides, they do not authorize using the Act based on a similar out of context reading to regulate executions.

Plaintiffs' Counts 2 and 3 are based on alleged violations of the FDCA, by the use of chemicals in executions by lethal injection by non-medical personnel without a prescription, and by the addition of saline solution to sodium thiopental powder by an anesthesiologist as opposed to a pharmacist, and by the use of chemicals not approved by the FDA for use in lethal injections without a prescription for off label use. Plaintiffs' Amended Complaint does not favor Defendants or the Court with an exact citation to which portions of the statute are allegedly being violated. But the portion of the statute dealing with prescriptions is in a section defining dispensing a drug that is safe for use only under the supervision of a physician, without a prescription, as a type of the prohibited conduct of misbranding a drug while holding it for sale. *See* 21 USC 353 (b) (1). This provision read in context has absolutely nothing to do with the conduct Plaintiffs are complaining about. It is a provision aimed at keeping pharmacists from dispensing prescription drugs as over the counter medication i.e.

misbranding. Reading the statute in context makes clear that this provision is not applicable to executions by lethal injection.

Similarly, it is difficult to see how a board certified anesthesiologist violates the FDCA by adding saline solution to an anesthetic powder in order to draw it up in a syringe. Plaintiffs do not assert what provision of the Act is allegedly violated by that conduct. But it strains plausibility that a physician is required to stop what he is doing and call in a pharmacist every time he adds saline solution or water to a powdered medicine in order to draw it up in a syringe.

Finally, Plaintiffs allege that the FDCA is violated because the chemicals not approved for use in lethal injections by the FDCA are used in lethal injections and the physician does not write a prescription for this off label use. The FDA does not approve chemicals use in lethal injections. *See Heckler v. Chaney,* 470 U.S. 821, 824-825 (1985). Therefore the only way to comply with Plaintiffs' reading of the Act would be for the physician to write a prescription. But writing a prescription for an item used in a lethal injection in the physician's presence would be a pointless act having nothing to do with the reason prescriptions are written. *See Gonzalez v. Oregon*, 546 U.S. at 274 (explaining the point of prescription requirements). As Plaintiffs have not favored Defendants or the Court in their Amended Complaint with a citation to the provision of the Act allegedly violated it is not possible to analyze that provision specifically. But again, the conduct complained of does not plausibly violate any provision in the Act, when the Act is read in context.

Further, the FDCA, like the CSA, contains no plain statement that it is intended to regulate to legal executions by the Several States. Like the use of controlled substances in physician assisted suicides discussed in *Gonzalez v. Oregon,* and *Oregon v. Ashcroft,* the use of controlled substances in executions cannot be viewed as regulated by the FDCA absent a plain and unmistakable statement that such was the intention of Congress, and none exists. The fact that the FDA itself does not view the Act as having a role in the context of executions is strong evidence that there is no plain statement that Congress intended the statute to regulate executions by lethal injections.

Counts 2 and 3 fail on the merits as a matter of law, both based on an in context reading of the text of the FDCA itself, and based on such a reading done in light of the plain statement rule.

Conclusion

Summary judgment should be granted for Defendants. In essence, Plaintiffs are taking federal statutes that were never intended to have anything to do with legal executions of criminals by the States, an area traditionally regulated by the States, not by Congress, and are complaining that the square pegs of execution procedures do not fit into the round holes of Acts of Congress not meant to have anything to do with execution procedures. This is exactly the type of analysis the United States Supreme Court criticized in *Gonzalez v. Oregon* in rejecting the theory that the prescription provisions of the CSA can be used to

regulate physician assisted suicides, an area that has nothing to do with the purpose of those prescription requirements. But the fact that Congress has not stated with unmistakable clarity its intention to have these Acts regulate executions by the States, as is required by the plain statement rule, eliminates any need for more detailed analysis of the alleged violations of the Acts themselves to determine that the Acts are not violated by the execution of criminals by the States. Also, Plaintiffs have not articulated an injury in fact they suffer because the square pegs of execution procedures allegedly do not fit neatly into the round holes of Acts of Congress that were never meant to have anything to do with execution procedures. If the physician started writing prescriptions for the execution chemicals, which is what Plaintiffs suggest is necessary for off label use of execution chemicals, and for injection of those chemicals by someone other than the physician, those pieces of paper would correct no real injury to Plaintiffs. Finally, as has been recognized by the courts that have rejected identical or similar claims, Congress intended that the FDCA and the CSA be enforced by the Federal Executive not, privately enforced against any defendants, including the States and their officials. That intention of Congress is itself fatal to Plaintiffs' case. For all these reasons Plaintiffs' claims all fail as a matter of law and summary judgment should be granted for Defendants on all counts and claims.

Respectfully submitted,

Chris Koster

Attorney General
/s/Michael J. Spillane

Michael Spillane
Assistant Attorney General
Missouri Bar No. 40704
P.O. Box 899
Jefferson City, MO 65102
Telephone: (573)751-7406
Facsimile: (573)751-2096

Certificate of Service

I hereby certify that a true and correct copy of the foregoing document was filed electronically on January 21, 2011 and should be served electronically on counsel for all Plaintiffs.

/s/Michael J. Spillane
Michael J. Spillane